Immediate Loading of 4 guided implants supporting a maxillary Overdenture using a Novaloc TiN retention system: Open ended prospective study

NCT06083506

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More Than Minimal Risk
Consent and HIPAA Form

Principal Investigator	Arif Salman Abdul Shakore
Department	Department of Periodontics
Protocol Number	#1801929813
Study Title	Immediate Loading of 4 guided implants supporting a maxillary Overdenture using a Novaloc TiN retention system: Open ended prospective study
Sponsor (if any)	STRAUMANN USA, LLC 60 Minuteman Road, Andover, MA 01810

Contact Persons

In the event you experience any side effects or injury related to this research, you should contact Arif Salman Abdul Shakore, Department of Periodontics, WVU School of Dentistry, PO Box 9490 Health Science North, Morgantown 26505, Phone number (304) 293-7429. If you have any questions, concerns, or complaints about this research, you can contact Dr. Salman Abdul Shakore at (304) 293-7429.

For information regarding your rights as a research subject, to discuss problems, concerns, or suggestions related to the research, to obtain information or offer input about the research, contact the Office of Research Integrity and Compliance at (304) 293-7073.

In addition, if you would like to discuss problems, concerns, have suggestions related to research, or would like to offer input about the research, contact the Office of Research Integrity and Compliance at 304-293-7073.

Introduction

You, _____, have been asked to participate in this research study, which has been explained to you by _____. This study is being conducted by in the Department of Periodontics at West Virginia University with funding provided by or sponsored by Straumann, USA.

Purpose(s) of the Study

The purpose of the study is to evaluate the clinical, radiographic and patient-related outcomes of implant-retained immediately-loaded maxillary complete dentures. Dentures are often esthetically and functionally not satisfying because of problems of retention and stabilization. Implant retained dentures are a good alternative treatment option because they solve these inconveniences. In this protocol, 4 dental implants are placed in the maxilla and the connection of the denture to the implants is performed immediately: this approach, called immediate-loading, helps to faster return to function and esthetics.

Description of Procedures

This study involves about 8 visits over a period of 12 months. If needed additional visits may be scheduled by your Study Doctor. It is important that you tell the dental/medical staff about any medication that you are taking before and during the study.

You will be asked to fill out a questionnaire regarding your denture. This will take approximately 10-15 minutes. You are free to answer only the questions you are comfortable to answer. You will have the opportunity to see the questionnaire before signing this consent form.

All the procedures performed during the study represent the standard of care in implant dentistry, except for the second CBCT after the implant placement, which constitutes the only investigational study procedure, aimed to evaluate the precision of the guided-surgery system.

If you are smoking, a maximum of 10 cigarettes per day are allowed. Elective treatment like implant surgery is not recommended if you are pregnant. Your Study Doctor must be informed immediately if you become pregnant. All the materials used in this study are approved by FDA. During the study, you will be asked if you have had any health problems since the last visit. If you choose to participate in this study, you will be asked to take medications that are part of standard clinical care. No experimental drugs will be used.

The 8 visits are the following:

- Visit 1 (Screening and pre-surgical planning). Informed consent will be signed. Medical/surgical history, Oral examination, intraoral photographs and CBCT will be performed and you will be evaluated for eligibility for participation in the study. You will be asked to fill a questionnaire regarding your denture.
- Visit 2 (Surgery). Implant placement and attachment of the denture will be performed. Intraoperative photographs and X-rays will also be taken. A second CBCT will be taken after the implant placement, for research purposes.
- Visit 3 (1-week post-surgery). Routine post-operative follow-up and care as required. Intraoperative photographs will also be taken.

- Visit 4 (2-week post-surgery). Routine post-operative follow-up. Intraoperative photographs will also be taken.
- Visit 5 (4-week post-surgery). Routine post-operative follow-up. Intraoperative photographs will also be taken.
- Visit 6 (12-week post-surgery). Routine post-operative follow-up. Intraoperative photographs will also be taken.
- Visit 7 (24-week post-surgery). Follow up visit. You will be asked to fill a questionnaire regarding your implantsupported maxillary overdenture. Intraoperative photographs and X-rays will also be taken.
- Visit 8 (12-month post-surgery). Follow up visit. You will be asked to fill a questionnaire regarding your implantsupported maxillary overdenture. Intraoperative photographs and Xrays will also be taken.

Risks and Discomforts

The risks for the participants are: dental implant failure and imprecise implant placement when compared to the presurgical planning.

Alternatives

You do not have to participate in this study. If you do not want to take part in the study, there are other alternatives, which included: no treatment, implant-supported dentures without participating in the study; non-implant supported conventional complete dentures; complete fixed implant supported prosthesis. Your Study Doctor can explain the options that are available to you if you decide not to take part in the study.

Benefits

The advantages of implant rehabilitations for the patients include: improved stability and retention of denture; increased masticatory efficiency; slower rate of bone ridge resorption. You may not receive any direct benefit from this study. The knowledge gained from this study may eventually benefit others.

Financial Considerations

You will not be paid for taking part in this study.

The standard care that you were already receiving prior to, and continue to receive during the study, will be charged to you/your insurance company as before. While the study has received partial funding to pay for many expenses, it cannot cover all the costs of this research. Some of the procedure costs will be charged to you: you will be responsible for the cost of a new denture if it is deemed necessary at the screening visit; at the time of the implant surgery you will pay $1500 for surgical implant placement and any denture modifications that will be done after.
If you have dental insurance, you may submit your payment receipt to your carrier to attempt to receive reimbursement. Please note that not all carrier cover implant treatment and if they do, they may reimburse you for only a portion of the procedure fee. We recommend that you contact your dental insurance carrier to determine your coverage benefits. You will be asked to return for follow up visit after 3, 6 and 12 months (visit 6, 7 and 8) after implant

placement. You will receive $100 for each scheduled follow up visit as reimbursement for travel expenses for a total of $300.

Your information may be provided to the appropriate parties for billing and/or payment purposes. Please be advised that any compensation received for participation in a research study, including a gift card, is considered taxable income and must be reported to the IRS. If you are a WVU employee or a WVU student-employee, you are required to report the total amount of compensation received for your participation in a research study to the WVU Tax Services Office upon receipt of payment.

Confidentiality

Any information about you that is obtained as a result of your participation in this research will be kept as confidential as legally possible. Your research records and test results, just like hospital records, may be subpoenaed by court order or may be inspected by the study sponsor or federal regulatory authorities without your additional consent. In any publications that result from this research, neither your name nor any information from which you might be identified will be published without your consent. The following procedures will be used to protect the confidentiality of your data. The study staff (principal investigator, research coordinator, co-investigators etc.) will keep all study records (including any codes to your data) locked in a secure location in a file cabinet in the office of the principal investigator. Research records will be labeled with a code. The code will be a sequential 3-digit number that reflects how many people have enrolled in the study. A master key that links names and codes will be maintained in an electronic file. The Informed Consent Form and HIPAA Authorization form will be stored in separate folders away from research data. All electronic files (e.g., database, spreadsheet, etc.) containing identifiable information will be password protected. Any computer hosting such files will also have password protection to prevent access by un-authorized users. Data that will be shared with the authorities of Straumann will be de-identified to help protect your identity. Information regarding your implant treatment, health information such as laboratory test results and dental X-rays are also kept in a dental record which will be stored at the University in a locked cabinet with restricted access. We will do our best to protect the confidentiality of the information we gather from you, but we cannot guarantee 100% confidentiality. You should know that the sponsor, Straumann, the Department of Health and Human Services, the Food and Drug Administration, the Health Center's Institutional Review Board and the Human Subjects Protection Office may inspect records. They may inspect records to ensure that the study is being done correctly. Also, if during the course of this study we learn of child, elder, or spousal abuse or of communicable diseases, we are required to report it to State officials. At the conclusion of this study the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations. Your data, health information, research results, specimens, or any and all other information related to this research study used in this research study may contribute to a new discovery or treatment. In some instances, your data, your health information, your research results, your specimens, these discoveries or treatments, or any other information related to this research study may be of commercial value and may be sold, patented, or licensed by the investigators and West Virginia University for use in other research or the development of new products. You will not retain any property rights nor will you share in any money that the investigators, West Virginia University, or their agents may realize.

HIPAA

We know that information about you and your health is private. We are dedicated to protecting the privacy of that information. Because of this promise, we must get your written authorization (permission) before we may use or disclose your protected health information or share it with others for research purposes.

You can decide to sign or not to sign this authorization section. However, if you choose not to sign this authorization, you will not be able to take part in the research study. Whatever choice you make about this research study will not have an effect on your access to medical care.

Persons/Organizations Providing the Information

Patient/West Virginia University Hospitals

Persons/Organizations Receiving the Information

- The research site carrying out this study. This includes UHA or UHA Affiliated, WVU, WVU Hospitals, West Virginia United Health System. It also includes each site's research staff and medical staff • Health care providers who provide services to you as part of this research study.
- Laboratories and other people and groups that look into your health information as part of this study in agreement with the study protocol.
- The United State Department of Health and Human Services (which includes the National Institutes of Health (NIH), Food and Drug Administration (FDA)) and other groups that have the right to use the information as required by law.
- Foreign Regulatory Agencies
- Straumann and the people and companies that they use to oversee, manage, or conduct the research.
- The members and staff of any Institutional Review Board (IRB) that oversees this research study.
- West Virginia University Office of Research Integrity and Compliance and Office of Sponsored Programs.

The Following Information Will Be Used

Information from your existing medical records and new information about you that is created or collected during the study such as: history and physicals, clinic visit notes, nursing and staff notes, laboratory results, x-rays, CBCT, demographic data, imaging scans and study forms.

The Information is Being Disclosed for the Following Reasons

- Review of your data for quality assurance purposes
- Publication of study results (without identifying you)
- Other research purposes such as reviewing the safety or effectiveness of the study drug and other products or therapies; conducting performance reviews of the study drug; evaluating other products or therapies for patients; developing a better understanding of disease; improving the design of future clinical trials

You May Cancel this Authorization at Any Time by Writing to the Principal Investigator

Your request should be addressed to:

Arif Salman Shakore, Department of Periodontics, WVU School of Dentistry, PO Box 9490 Health Science North, Morgantown 26505

If you cancel this authorization, any information that was collected already for this study cannot be withdrawn. Once information is disclosed, according to this authorization, the recipient may redisclose it and then the information may no longer be protected by federal regulations.

You have a right to see and make copies of your medical records. You will not be able to see or copy your records related to the study until the sponsor has completed all work related to the study. At that time you may ask to see the study doctor's files related to your participation in the study and have the study doctor correct any information about you that is wrong.

This authorization will expire at the end of the study unless you cancel it before that time.

Voluntary Participation

Participation in this study is voluntary. Before making a decision about whether to participate in this research study, please read this consent form carefully and discuss any questions you have with the researcher. You may also want to talk to family members, your primary care physician or a friend before making a decision.

If you decide to participate in the study, you are free to withdraw from it at any time. If you decide not to participate or you withdraw from the study, your decision will not affect your present or future medical care you receive at WVU and there will be no penalty or loss of benefits to which you are otherwise entitled.

If you decide to withdraw, we ask that you let us know by calling Dr. Arif Salman Shakore at 304-293-7429 or by sending a written notice to Dr. Arif Salman Shakore of Department of Periodontics, Room 1070 HSC North P.O. Box 9490, Morgantown, West Virginia 26506.

The researcher and Straumann may prevent you from continuing in this study. This may happen if:

- You become ineligible to continue in the study,
- You fail to follow the instructions of the Study Doctor,
- You experience a failure of all the implants,
- You experience a study related injury.

When you stop taking part of the study you will be required to go through the termination procedures the Study Doctor considers necessary for your safety. This may include attending a premature discontinuation visit to assess your medical condition and ensure your safety.

Risk of Injury

If you are injured as a result of this research, treatment will be available. This care will be billed to you or your insurance company. There is no commitment to provide any compensation for research-related injury. You should realize, however, that you have not released this institution from liability for negligence. Please contact the investigator, Dr. Arif Salman Shakore, at 304-293-7429 if you are injured or for further information.

You have been given the opportunity to ask questions about the research, and you have received answers concerning areas you did not understand.

Upon signing this form, you will receive a copy.

I willingly consent to participate in this research.

Signatures

You have been given the opportunity to ask questions about the research and your authorization of HIPAA, and you have received answers concerning areas you did not understand. Upon signing this form, you will receive a copy.

Participant Signature

I willingly consent to participate in this research and authorization of HIPAA.

Signature of Subject or Subject's Legal Representative

Printed Name Date

Consenting Individual Signature

The participant has had the opportunity to have questions addressed. The participant willingly agrees to be in the study.

Signature of Person Obtaining Informed Consent

Printed Name Date